Introduction

PCORI requires meaningful engagement with stakeholder groups throughout the research process—from topic selection through design and conduct of research to dissemination of results. A well-thought-out engagement plan can facilitate the successful execution of an engaged research project. Recognizing that many aspects of a study’s engagement plan may change or further develop between the submission of the research application and the start of a study, PCORI requires awardees to submit an updated engagement plan within six months from the project’s contractual start date.

The purpose of this template is to:

- Guide the study team in operationalizing the engagement strategy that was described in the application. The study’s updated engagement plan should serve as a useful resource that aids the team in fulfilling the objectives of a patient- and stakeholder-driven health research study.
- Assist PCORI in documenting engagement activities at the project level in order to examine the influence and impact of engagement on study outcomes.

Instructions

This template is divided into sections that PCORI has found to be important components of stakeholder engagement in patient-centered outcomes research. All sections of this template should be completed to the best of your ability and to the extent they are applicable to the engagement plan for your project. PCORI does understand however that certain sections may not apply to your project design based on your study’s unique needs, goals, and objectives. Please indicate “N/A” in sections that are not applicable.

Please fill out this template and submit it as an attachment to the “Submit Updated Engagement Plan in PCORI Online” milestone in PCORI Online by the milestone’s due date. Note that PCORI began requiring this milestone with Cycle 3 2016 awardees. Please contact your program officer if you have any questions or need clarification.
1. **Background Information**

- **Principal Investigator:** [Enter text]
- **Project Title:** [Enter text]
- **Contract ID Number:** [Enter text]

**Stakeholders Engaged** (check all that apply):

- [ ] Patients/Consumers
- [ ] Family Caregivers
- [ ] Patient/Caregiver Advocacy Organizations
- [ ] Community-Based Organizations
- [ ] Clinicians
- [ ] Clinics/Hospitals/Health System Representatives
- [ ] Purchasers
- [ ] Payers
- [ ] Life Sciences Industries
- [ ] Policy Makers
- [ ] Training Institutions
- [ ] Subject Matter Experts
- [ ] Other, Please Specify: [Enter text]

Please consider each engaged group within your project in your responses. [Click here] for additional information about how PCORI defines stakeholders.
2. Goals

To arrive at a shared vision for engagement, work with your study team and stakeholder partners to draft engagement-specific goals for your study. In the process, think about critical study activities that would benefit from engagement.

- What all does your study team hope to accomplish through engagement with stakeholders? Be specific in your response (e.g., enhance study recruitment and retention strategies, develop strong patient/community partnerships to support future research, explore innovative approaches to conducting engaged research, etc.). Please respond below.

- What do partners hope to gain from their participation? What goals do they have that may be different from the study team? (Goals of individual partners can be included in their bios in the next section). Please respond below.
### 3. Partner Roster, Bios, and Roles

Please provide a roster of members of the patient and stakeholder advisory bodies (e.g., patient advisory board, stakeholder advisory committee) and individuals who are advising the study team. Below is an example of a table that can be used to present the information, if there are alternate formats which better suit your stakeholders/study, their use is encouraged.

<table>
<thead>
<tr>
<th>Name (include degree, if applicable)</th>
<th>Email address</th>
<th>Organization (if applicable)</th>
<th>Role, (workgroups, activities)</th>
<th>Bio &amp; Goals (3-5 sentences)</th>
<th>Preferred name for PCORI website*</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g., Jane Doe</td>
<td><a href="mailto:e.g.jdoe@yahoo.com">e.g.jdoe@yahoo.com</a></td>
<td>N/A</td>
<td>e.g., Patient &amp; Caregiver Stakeholder Committee, Data Analysis Workgroup</td>
<td>e.g., Jane Doe is a patient partner who has been living with MS since the age of 51. She has used many different therapies and strategies to manage her pain and improve functionality. By participating in this study, she hopes to advocate for other MS patients who are frustrated with current treatment options, and learn more about the treatment options that have worked for other MS patients</td>
<td>e.g., Jane Doe, patient partner; John Doe, MPA, Director of Advocacy, American Lung Association</td>
</tr>
</tbody>
</table>

*NOTE: Partners should be made aware that PCORI recognizes the contributions of stakeholder partners by posting the individual names of partners on the study’s project page on the PCORI website. If, for privacy reasons, partners elect not to be listed publicly on our website, please indicate this on the roster. An example of a PCORI project page that lists patient and stakeholder partners can be viewed [here](#).
4. Engagement Structure

Please provide a diagram depicting patient and stakeholder advisory bodies and/or roles and their relationship to study leadership, other study governance committees, and key consultants in order for PCORI to understand how engagement is integrated into study governance. This should be a comprehensive visual representation of all the entities involved in your study and should include stakeholders’ and investigators’ lines of communication and information flows, and how patient and other stakeholder partner groups report feedback to decision-making authorities on the study. If applicable, please include project staff designated to plan and oversee engagement activities in your diagram.

**NOTE:** complex engagement structures do not necessarily result in better engagement. The purpose of the diagram is to document the different engagement models and strategies in PCORI’s portfolio.

Please include a diagram below or as an attachment.
5. Proposed Meeting and Key Activity Timeline

Considering the study governance and advisory bodies described in question 4, please indicate in the chart below the ways in which these groups will come together for collaboration throughout the study. Note that frequency and purpose of meetings and other engagement activities may vary over the course of the study. For example, some projects may choose to hold meetings more frequently in the early stages of the study and reduce the frequency when needs are less intense.

Please complete the table below:

<table>
<thead>
<tr>
<th>Stakeholder advisory body or other engagement activity</th>
<th>How frequently are groups meeting or activities occurring?</th>
<th>What is the setting?</th>
<th>What is the purpose of the meeting or engagement activity?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the advisory body or other engagement method.</td>
<td>Fill in the frequency of either the meeting or activity (e.g., monthly, quarterly, as needed).</td>
<td>Detail the setting for meetings and/or activities. Where are they occurring?</td>
<td>What are your goals and planned outcomes for the meeting or activity? What will partners be asked to contribute?</td>
</tr>
<tr>
<td>e.g., Community Advisory Board</td>
<td>e.g., Quarterly</td>
<td>e.g., Community public library in person</td>
<td>e.g., Year 1: input on protocol development, finalizing outcome measures; Year 2: recruitment strategies; Year 3: Data analysis and dissemination</td>
</tr>
<tr>
<td>e.g. community forum</td>
<td>e.g. once at study kick-off; once at study conclusion</td>
<td>e.g. conference space at medical center</td>
<td>e.g. study kick-off: refine study outcome measures; study conclusion: share study findings</td>
</tr>
<tr>
<td>e.g. survey of targeted group of patient advocates</td>
<td>e.g. once, within first 3 months of study</td>
<td>e.g. online via email invite</td>
<td>e.g. to gather input and feedback on enrollment script</td>
</tr>
</tbody>
</table>
6. Preparation

Orientation: An orientation for partners can be helpful to level-set expectations and enable successful participation. Orientations can include some or all the following:

- Expectations and guidance for involvement (e.g. job descriptions, memoranda of understanding, committee charters or agreements that may address team management issues such as decision-making)
  NOTE: If using memoranda of understanding, committee charters or agreements, or job descriptions, please attach it to the completed template

- Technical and logistical information (e.g. how partners will be paid, directions to meeting locations or use of virtual meeting platforms, study team rosters with contact information)

How will the study team orient stakeholder partners to the study? Please respond below.

Training/education: Programmatic or content-related training and education provided to patient and stakeholder partners should align with your study design and how partners will be involved in the project. Please address the questions below.

- What kind of training or education, if any, will be provided to prepare partners for participation in the various stages of the research process? (e.g., PCORI’s free, online training, Research Fundamentals, Collaborative Institutional Training Initiative (CITI), or other workshops or webinars on the research process) Please also address the frequency of these trainings (e.g., pre-award, kick-off meeting, periodic, ad hoc). Please respond below.

- What efforts, if any, are research team members making to learn about best practices for working with partners of diverse backgrounds and limited research knowledge? Please respond below.
7. Recruitment and Retention

Please describe activities or strategies for stakeholders to support recruitment and retention of study participants (e.g., providing input on the design of study materials, participating in the content of recruitment videos, pilot-testing the recruitment script and process, selecting recruitment sites, or troubleshooting recruitment challenges). Please respond below.
8. Engagement Process and Outcomes Monitoring

To ensure a productive and collaborative working relationship amongst study team members, it can be helpful to continually assess the efficiency and effectiveness of the team’s engagement activities. This can occur by monitoring the effect of engagement on achieving study milestones, measuring the progress on engagement-specific goals, and/or evaluating the experience of stakeholders. Common approaches to this type of monitoring include conducting annual surveys or feedback sessions to learn about what is working and not working in terms of engagement practices, event-specific surveys or follow-up tools like a suggestion box, and one-on-one interviews and informal group discussions. Please describe your research team’s plan for evaluating engagement activities and contributions.
9. Return of Research Results

PCORI asks awardees to share the aggregate results of the research study with research participants. The planning of research results return can start early in the project and patient and stakeholder partners can assist with creating approaches and shaping messages. Please respond below to indicate how the study team plans to return research results to study participants. (For more information, click here)
Frequently Asked Questions:

- Where do I find tools and resources to help with different components of engagement in my study?
  PCORI’s website has many resources that can be helpful throughout the phases of a PCOR study: Research Fundamentals is a free, on-demand training for patients and stakeholders who are new to research and want to learn more about the process; the Engagement Tool and Resource Repository is a searchable repository of engagement-related tools that have been developed and used by PCORI awardees; the Engagement in Health Research Literature Explorer is a searchable list of publications on engagement in health research, sortable by article topic type, types of stakeholders engaged, and phase(s) of research in which engagement occurred, from identifying research questions to sharing study results. Many more resources are available here.

- Who should I include in my stakeholder roster? Include anyone who participates in advisory board/committee meetings, such as the stakeholder types listed in Section 1. Additionally, you may choose to include study staff and/or contractors, especially those who will be working directly with the stakeholders and/or the engagement process. If study staff and/or contractors are included in the roster, please mark their role accordingly.

- What is the difference between Orientation and Preparation?
  - Orientation is intended to include information on role expectations and level of involvement as well as key logistical details about where interactions will take place, how they will take place, and how payment will occur. Also include when the orientation occurs, the platform by which it occurs (e.g., virtual or in-person), and the materials presented (document of expectations, etc.).
  - Preparation is intended to include activities to build knowledge and skills for your stakeholders to better participate in the research process, or as an informed stakeholder within a specific disease or condition area. Also include information on the frequency, platform, materials, and the source of these trainings (developed by your study team, adapted from an external source).

- Can a stakeholder fall into more than one of the categories PCORI provides?
  We realize that individuals may be members of several communities. For example, a nurse who practices direct patient care in a residency program attached to a hospital could present the viewpoint of clinicians, hospital and health systems, or training institutions, or even a patient. We ask that stakeholder partners identify the viewpoint they primarily represent.

- We haven’t discussed specific ways our stakeholders will help with Recruitment and Retention yet, what do I put? Discussing these activities with your stakeholders to learn where they feel most comfortable lending a hand is a great strategy. You can simply
indicate that this discussion has yet to take place and include the expected date, if available.

- **I already have a stakeholder roster ready to go, do I have to use the table provided?** If you have *any* of this information already written up you are welcome to insert it into/attach it to this template, though we advise that you carefully review the prompts to ensure all aspects of the question are addressed.

- **What is results return and where can I find additional information?** Results return refers to the process of returning the aggregate results of your research study back to the participants who took part in it. In fulfillment of our ethical responsibility, PCORI explicitly directs researchers to provide aggregate results to study participants. This activity is described in our [Process for Peer Review of Primary Research and Public Release of Research Findings](https://www.pcori.org/process-peer-review-primary-research-public-release-research-findings), adopted by our [Board of Governors](https://www.pcori.org/board-governors) in February 2015. PCORI encourages early planning for results return; if you received PCORI funding in 2020 or later, you will have budgeted for results return as part of your application and should obtain IRB approval sooner rather than later. For more information, please see the [PCORI Help Center FAQs](https://www.pcori.org/help-center/faqs) or email ResultsReturn@pcori.org.